

**REMARKS/ARGUMENTS**

Claims 44-50 are pending in this application. Claims 44-50 have been amended herein to help address the 35 U.S.C. § 112 rejections. Specifically, the claims have been amended to clarify that the specific type of cells (dendritic cells), the specific nature of the growth factors (TNF alpha and GM-CSF), and that an antigen triggers an antigen-specific immune response. Support for the term "antigen" can be found in, e.g., page 10, line 25. Support for the phrase "immune response" can be found in, e.g., page 10, line 30-31. Support for co-culturing T cells with the antigen presenting dendritic cells can be found in, e.g., page 12, line 31. Claims 1-43 and 51-72 have been cancelled either previously or in this Amendment. Claims 44-50 stand rejected. The issues raised in the Office Action of March 22, 2011 ("Current Action") are as follows:

- \* Claims 44-50 rejected under 35 U.S.C. § 112, second paragraph, as being indefinite;
- \* Claims 44-50 rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification, written description;
- \* Claims 44-50 rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification, enablement; and
- \* Claims 44-47 and 50 are rejected under 35 U.S.C. § 103(a) as being unpatentable.

In response, Applicant(s) respectfully traverse(s) the outstanding claim rejections and requests reconsideration and withdrawal in light of the remarks presented herein.

***REJECTIONS UNDER 35 § U.S.C. § 112***

***Claims 44-50 rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.***

The claims have been amended to overcome the rejection. Applicant(s) respectfully request(s) that the Examiner withdraw the rejection of Claims 44-50 under 35 U.S.C. § 112 second paragraph.

***Claims 44-50 rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification, written description.***

The claims have been amended to overcome the rejection. Applicant(s) respectfully request(s) that the Examiner withdraw the rejection of Claims 44-50 under 35 U.S.C. § 112 first paragraph.

***Claims 44-50 rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification, enablement.***

The claims have been amended to overcome the rejection. Applicant(s) respectfully request(s) that the Examiner withdraw the rejection of Claims 44-50 under 35 U.S.C. § 112 first paragraph.

***REJECTIONS UNDER 35 U.S.C. § 103***

***Claims 44-47 and 50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over (T.F. Proc. Nat'l. Acad. Sci., USA 1996; 93:2588-2592) by Zhou and Tedder in view of (Immunotherapy of cancer using dendritic cells, 1997) by Morse and Lyerly.***

Claims 44-47 and 50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over (T.F. Proc. Nat'l. Acad. Sci., USA 1996; 93:2588-2592) by Zhou and Tedder (hereinafter Zhou and Tedder) in view of (Immunotherapy of cancer using dendritic cells, 1997) by Morse and Lyerly (hereinafter Morse and Lyerly).

To render a claim unpatentable under 35 U.S.C. § 103, all the claim limitations must be taught by the prior art, M.P.E.P. § 2143.03. Moreover, the Examiner must provide analysis supporting any rationale why a person skilled in the art would combine the prior art to arrive at the claimed invention, and "[such] analysis should be made explicit," *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 82 U.S.P.Q.2d 1385 (2007). The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness, M.P.E.P. § 2142; *In re Peehs*, 204 U.S.P.Q. 835, 837 (CCPA 1980). As the applied art does not meet all the claim limitations and the Examiner has not provided proper analysis supporting rationale why a person skilled in the art would have combined the applied art to arrive at the claimed invention, a *prima facie* case of obviousness has not been established with respect to the present claims.

Applicants traverse the rejection as these references do not include each and every element of the claimed invention and a motivation to combine them in a manner that would provide the skilled artisan with a reasonable expectation of success. As previously discussed, antigen processing and presentation in the context of an antigen-specific immune response is not the same process for T cell activation as a mixed lymphocyte reaction (MLR) (the Pickl reference). The present invention leads to antigen-specific, antigen presenting cells and not a generic mixed lymphocyte reaction that is not antigen specific. Attached as Exhibit A is the definition for a mixed lymphocyte reaction (MLR) from the Dictionary of Immunology, that describes the T cell activation event as occurring between "allogeneic leukocytes" that recognize "allogeneic CLASS II MAJORHISTOCOMPATIBILITY MOLECULES of the other set and undergo proliferation and differentiation... ." Thus, as in the prior art, the MLR used by not an antigen specific response, but rather, a non-specific response typical of transplant rejection or graft versus host disease. As with Pickl, the Zhou and Tedder references teach a reaction that is different from the present invention. The Zhou and Tedder references use GM-CSF and TNF alpha in combination with cyclosporine, which is a well-known immunosuppressing drug widely used to reduce the activity of the patient's immune system. Nothing in the Morse and Lyerly references teach against the use of cyclosporin. Following the teachings of Zhou and Tedder, in combination with Morse

and Lyerly, the outcome that would be expected is the immune suppression of the cyclosporine eliminating an immune response. Thus, the combination fails to support a *prima facie* case of obviousness.

Accordingly, claims 44-47 and 50 are not anticipated by, or rendered obvious from Zhou and Tedder and Morse and Lyerly, or any combination thereof. Applicant(s) respectfully request(s) the Examiner withdraw the rejection under 35 U.S.C. § 103(a).

## CONCLUSION

In light of the remarks and arguments presented above, Applicant(s) respectfully submit(s) that the claims in the Application are in condition for allowance. Favorable consideration and allowance of the pending claims 44-50 are therefore respectfully requested.

In view of the above, Applicant(s) believe(s) the pending Application is in condition for allowance. Applicant(s) believe(s) this paper is being filed with all required fees. However, if any additional fee is due, including those for an extension of time please charge any fees required or credit any overpayment to Chalker Flores, LLP's Deposit Account No. 50-4863 during the pendency of this Application pursuant to 37 CFR 1.16 through 1.21 inclusive, and any other section in Title 37 of the Code of Federal Regulations that may regulate fees. If an extension of time is required with this response but is not included, Applicant(s) hereby petition for a Request for Extension of Time under 37 CFR 1.136(a).

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: June 22, 2011

Respectfully submitted,  
CHALKER FLORES, LLP



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